THE SOCIETY OF THORACIC SURGEONS

633 N. SAINT CLAIR STREET, SUITE 2320
CHICAGO, ILLINOIS 60611-3658
Phone: 312.202.5800
Fax: 312.202.5801
E-mail: sts@sts.org
Web: http://www.sts.org

THE SOCIETY OF THORACIC SURGEONS

STATEMENT BEFORE THE FOOD AND DRUG ADMINISTRATION

CIRCULATORY SYSTEM DEVICES PANEL

OF THE MEDICAL DEVICES ADVISORY COMMITTEE

October 26, 2011

The Society of Thoracic Surgeons (STS) is pleased to have the opportunity to submit the following comments as the FDA Circulatory System Devices Panel considers the premarket approval application sponsored by AtriCure, Inc., for the AtriCure Synergy Ablation System to be used for the treatment of atrial fibrillation in patients who are undergoing open concomitant cardiac surgery.

STS is the largest professional society representing cardiothoracic surgeons in the United States and internationally. STS represents more than 6,200 surgeons, researchers and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest.

Atrial fibrillation is the most common sustained cardiac rhythm disturbance and its prevalence increases with age. An estimated 2.5 million people have the condition in the United States. Atrial fibrillation may occur with or without structural heart disease. Significant morbidity, mortality, and health care costs are associated with the condition. The patient's clinical condition often deteriorates owing to the hemodynamic compromise associated with the arrhythmia, and the thromboembolic events directly related to the arrhythmia can be devastating.

Medical treatment with antiarrhythmic drugs, electrical cardioversion, rate control medications, and anticoagulation follows evidence-based guidelines established by a panel of experts from the American College of Cardiology, the American Heart Association, and the European Society of Cardiology while surgical approaches to the treatment of atrial fibrillation can be traced to the nearly 20 year success rate of the Cox-Maze procedure and subsequent innovations.

In response to a need for more information about the efficacy of interventional and surgical approaches to treat atrial fibrillation, the Heart Rhythm Society, The Society of Thoracic Surgeons, The American College of Cardiology, European Heart Rhythm Association, and the European Cardiac Arrhythmia Society jointly published an *Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation*[1]. This document includes specific recommendations for performing atrial fibrillation ablation at the time of other cardiac operations, and for performing standalone atrial fibrillation ablation by both electrophysiologists and surgeons.

In brief, the societies agree that atrial fibrillation ablation is recommended in: 1) Symptomatic AF patients undergoing other cardiac surgical procedures and 2) Selected asymptomatic AF patients undergoing cardiac surgery in whom the ablation can be performed with minimal risk. Stand-alone atrial fibrillation surgery should be considered for symptomatic AF patients who prefer a surgical approach, have failed one or more attempts at catheter ablation, or are not candidates for catheter ablation.

Both this document, and STS's *Guidelines for Reporting Data and Outcomes for the Surgical Treatment of Atrial Fibrillation*[2], report specific guidelines for reporting data and outcomes. The consensus statement with the Heart Rhythm Society also creates a similar set of reporting guidelines that both the electrophysiologists and surgeons will use to report their outcomes in the future.

[1] http://www.sts.org/sites/default/files/documents/pdf/guidelines/HR_Afib_Ablation.pdf
[2] http://www.sts.org/sites/default/files/documents/pdf/guidelines/GuidelinesforReportingDataandOutcomesfortheSurgicalTreatment.pdf

The STS Workforce on Evidence Based Surgery has encouraged the adoption of these guidelines for reporting clinical results derived from patients undergoing surgical procedures for atrial fibrillation. Adoption of these guidelines will greatly facilitate the comparison between the reported experiences if various authors, treating different cohorts of patients at different times with different techniques and energy sources. The analysis of the burden of atrial fibrillation will evolve as continuous monitoring becomes clinically available. These guidelines are also appropriate for catheter-based treatment of atrial fibrillation. Thus, more reliable evaluation and comparisons of surgical results will advance our knowledge and further the development and application of these procedures to the large population of patients with atrial fibrillation.

STS believes that atrial fibrillation is a significant health care problem in the United States and those technologies that are shown to be effective in the treatment of atrial fibrillation are made available to health care practitioners.

STS has long been at the forefront of efforts to improve healthcare quality. The STS National Database (Database) was established in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are three components to the Database, each focusing on a different area of cardiothoracic surgery—

- Adult Cardiac Surgery Database;
- General Thoracic Surgery Database; and
- Congenital Heart Surgery Database

The component databases provide opportunities for quality improvement to their participants. STS has developed quality performance measures in all three sub-specialties of surgery, and these measures have either been endorsed or are in the process of being considered for endorsement by the National Quality Forum. By collecting outcomes data for submission to the Database, surgeons are committing to improving the quality of care that their cardiothoracic surgery patients receive. The Database has the corollary potential to be a powerful tool for clinical research. Since its inception, more than 100 publications have been derived from Database outcomes. These studies have been published in a variety of professional journals and textbooks and have significantly advanced knowledge in cardiothoracic surgery.

The Database continues to expand with new initiatives. Launched in January 2011, STS Public Reporting Online enables Database participants to voluntarily report to the public their heart bypass surgery performance. Overall composite star ratings as well as their component ratings are listed on www.sts.org for more than 250 Database participants. The Adult Cardiac Surgery Database, now containing more than 4.5 million surgical records, represents an estimated 94 percent of all adult cardiac surgery centers across the U.S. With the success of participation nationally, STS launched in 2011 an initiative to accommodate Database participation worldwide by including international participants in the Adult Cardiac Surgery Database.

Duke Clinical Research Institute (DCRI) is the data warehouse and analysis center for the Database. The DCRI team brings the Database a wealth of experience and knowledge in the area of outcomes management. On behalf of the STS, DCRI develops participant-specific reports that provide analysis of participants' adult cardiac surgery outcomes. These reports benchmark each participant's data against regional and national outcomes displayed in both graphic and tabular format. Reports are available to participants in electronic web based format.

In general, the Database provides:

- A standardized format for examining the care of patients undergoing cardiothoracic operations;
- A tool that can be used to target specific areas for clinical practice improvement;
- The ability to obtain an accurate reflection of practice patterns;
- The ability to research the national aggregate data set; and
- The opportunity to participate in a national quality improvement effort for thoracic surgery that has an impact at the local, regional, and national levels.

STS envisions a health care system that reinforces meaningful quality improvement initiatives, including the acquisition and use of risk-adjusted reliable outcomes and clinical effectiveness data, and reward physicians for improved outcomes. Successful implementation relies on the integration of clinical and administrative data, allowing researchers to monitor the cost of care over time and provide an assessment of clinical and cost effectiveness, including issues related to new technologies and devices. However, only a clinical database with a sufficient volume of clinical records can be credibly risk-adjusted for case mix to yield accurate and comparable findings. STS has successfully linked its clinical data with Centers for Medicare and Medicaid Services (CMS) MEDPAR information to obtain longitudinal outcomes data for a wide array of cardiothoracic surgery operations. The ability to link clinical data with administrative data has opened up important new ways to assess the effectiveness of treatment options and offered new avenues for medical research. Clinical data yield sophisticated risk-adjustment assessments, while administrative data provide information on long-term outcomes such as mortality rate, readmission diagnoses, follow-up procedures, medication use, and costs. Linked data are particularly useful in conducting comparative effectiveness research.

It is clear that clinical registries can and should be utilized to execute meaningful comparative effectiveness research along with pre and postmarket surveillance of new medical devices in the marketplace. Further, combining clinical and administrative data allows for real time data collection and analysis. Without any added effort you can track where the new medical device has been used, for what purpose, and for whom (patient demographics) in both the pre and postmarket settings. Such robust data will help researchers to be able to identify any anomalies, hone in on the causes of adverse events, and (if the device has raised concerns after going to market) the reason for the change in outcomes. The registry-based process will allow for regulators to build longitudinal analysis into the new framework as the registry's data collection will be ongoing throughout the lifetime of the device and the patients who have benefitted from it. Clinical registries augmented with administrative data are the best equipped to design and implement risk-based analysis. Such a process has been a key component of the success of the Database.

STS supports innovative approaches to assist FDA to evaluate appropriate data with which to monitor and understand new technologies. We believe that the primary function of a post-market surveillance program is to provide a mechanism for monitoring the safety and efficacy of devices as they are released for clinical use in the market. It is imperative to have a post-market surveillance program in place to promptly identify and respond to any potential problems.

STS believes that there is a genuine need for contemporaneous data, and encourages utilizing observational populations representative of clinical practice to more completely assess medical and financial effectiveness of therapies that will optimize patient safety surrounding new technology introduction and adoption. Active, robust comprehensive databases, like the Database, should form the basis of partnerships between FDA and medical societies to assist FDA in evaluation of patient safety and clinical benefit issues surrounding new technology adoption into clinical practice.

STS believes that clinical registries have a significant role to play in many health care innovations. If registries are built appropriately, they can accommodate all types of reform: from the execution of new payment models to the successful, real-time execution of comparative effectiveness research and post-market surveillance. This is because clinical registries are built with the goal of assessing, identifying, and promoting the provision of high quality, cost effective care. In fact, when they are designed to accommodate all these reforms, they are actually more effective than when they are designed for a more narrow focus. We look forward to the opportunity to work with FDA and policy-makers to develop a new regulatory framework that builds on existing knowledge and that bolsters the health care system as a whole.